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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,334	08/06/2001	Tian Xu	6523-020-999	5438

7590 01/27/2004

Pennie & Edmonds
1155 Avenue of the Americas
New York, NY 10036-2711

EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/763,334	XU ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondenc address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-113* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Re: Xu *et al.*

Claims 1-113 are pending.

Note: Upon review and reconsideration, the restriction/election requirement mailed 01/24/2003 is vacated. A new restriction requirement is set forth below:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, drawn to the special technical feature of a recombinant non-human animal with inactivated lats gene.

Group 2, claim(s) 6-12, and 37, drawn to the special technical feature of a method for screening a compound for activity in treating or preventing cancer comprising administering a compound to the recombinant non-human animal.

Group 3, claim(s) 13, drawn to the special technical feature of a method for screening a compound for activity in treating or preventing cancer comprising recombinantly expressing the compound in the recombinant non-human animal.

Group 4, claim(s) 14-22, 37 drawn to the special technical feature of a method for screening a compound for activity in treating or preventing **skin** cancer comprising administering a

compound to a *lats* knock-out animal having skin tumors induced by exposure to at least one carcinogen.

Group 5, claim(s) 23, drawn to the special technical feature of a method for screening a compound for activity in treating or preventing **skin** cancer comprising recombinantly expressing the compound in a *lats* knock-out animal having skin tumors induced by exposure to at least one carcinogen.

Group 6, claim(s) 24-35, 37, drawn to the special technical feature of a method for screening a compound for activity in treating or preventing **a disease or disorder associated with pituitary dysfunction** comprising administering a compound to a *lats* knock-out animal.

Group 7, claim(s) 36, drawn to the special technical feature of a method for screening a compound for activity in treating or preventing **a disease or disorder associated with pituitary dysfunction** comprising recombinantly expressing a compound in a *lats* knock-out animal.

Group 8, claim(s) 38-42, 44-49, 53-59 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a lats protein wherein said protein is SEQ ID NO:2 or is associated with proteins encoded by SEQ ID NO:1.

Group 9, claim(s) 38-41, 44-48, 53-59 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a lats protein wherein said protein is SEQ ID NO:4 or is associated with proteins encoded by SEQ ID NO:3.

Group 10, claim(s) 38-41, 44-48, 53-59 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a lats protein wherein said protein is SEQ ID NO:6 or is associated with proteins encoded by SEQ ID NO:5.

Group 11, claim(s) 38-41, 44-48, 53-59 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a lats protein wherein said protein is SEQ ID NO:8 or is associated with proteins encoded by SEQ ID NO:7.

Group 12, claim(s) 38-39, 43, 50-51, 53-59 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a lats analog or derivative that has activity to promote lats function.

Group 13, claim(s) 38-39, 52-59 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising

administering to a subject a chimeric protein with lats-associated amino acids and non-lats associated amino acids.

Group 14, claim(s) 38-39, 60-66 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a nucleic acid wherein said nucleic acid is SEQ ID NO:1 or the reverse complement thereof.

Group 15, claim(s) 38-39, 60, 63 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a nucleic acid that hybridizes under low stringency conditions to a second nucleic acid that is the reverse complement of SEQ ID NO:3.

Group 16, claim(s) 38-39, 60, 63 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a nucleic acid that hybridizes under low stringency conditions to a second nucleic acid that is the reverse complement of SEQ ID NO:5.

Group 17, claim(s) 38-39, 60, 63 drawn to the special technical feature of a method for treating a cancer that has been shown to be refractory to a chemotherapy or radiation therapy comprising administering to a subject a nucleic acid that hybridizes under low stringency conditions to a second nucleic acid that is the reverse complement of SEQ ID NO:7.

Group 18, claim(s), 67, drawn to the special technical feature of a kit comprising in one or more containers a therapeutically effective amount of a molecule wherein said molecule is a lats protein and at least one chemotherapeutic agent.

Group 19, claim(s), 67, drawn to the special technical feature of a kit comprising in one or more containers a therapeutically effective amount of a molecule wherein said molecule is a lats derivative and at least one chemotherapeutic agent.

Group 20, claim(s), 67, drawn to the special technical feature of a kit comprising in one or more containers a therapeutically effective amount of a molecule wherein said molecule is a lats analog and at least one chemotherapeutic agent.

Group 21, claim(s), 67, drawn to the special technical feature of a kit comprising in one or more containers a therapeutically effective amount of a molecule wherein said molecule is a nucleic acid encoding a lats protein, derivative, or analog thereof and at least one chemotherapeutic agent.

Group 22, claim(s), 68-72, 89-90, drawn to the special technical feature of a purified complex of a lats protein and a cdc2 protein and a pharmaceutical composition thereof.

Group 23, claim(s), 73-77, 91 drawn to the special technical feature of a purified complex selected from the group consisting of a complex of a derivative of a lats and a cdc2 protein, a complex of a lats protein and a derivative of a cdc2, and a complex of a derivative of a lats protein and a derivative of a cdc2 protein.

Group 24, claim(s), 78-81, 92 drawn to the special technical feature of a chimeric protein comprising a fragment of a lats protein consisting of at least 6 amino acids fused via a covalent bond to a fragment of a cdc2 protein consisting of at least 6 amino acids.

Group 25, claim(s), 82-83, 93 drawn to the special technical feature of an antibody which binds to a purified complex of a lats protein and a cdc2 protein.

Group 26, claim(s) 84-85, 87, 94, 96, 98 drawn to the special technical feature of an isolated nucleic acid or an isolated combination of nucleic acids comprising a nucleotide sequence encoding a lats protein and a nucleotide sequence encoding a cdc2 protein, methods of making such proteins, and pharmaceutical compositions thereof.

Group 27, claim(s) 86, 88, 95, 97 drawn to the special technical feature of an isolated nucleic acid that comprises a nucleotide sequence encoding a chimeric protein comprising a fragment of a lats protein consisting of at least 6 amino acids fused via a covalent bond to a fragment of a cdc2 protein consisting of at least 6 amino acids, and a pharmaceutical composition thereof.

Group 28, claim(s) 99, drawn to the special technical feature of a method of diagnosing or screening for the presence of or a predisposition for developing a disease or disorder characterized by an aberrant level of a complex of a lats protein and a cdc2 protein in a subject comprising measuring the level of said complex or functional activity of said complex in a sample derived from said subject.

Group 29, claim(s) 99, drawn to the special technical feature of a method of diagnosing or screening for the presence of or a predisposition for developing a disease or disorder characterized by an aberrant level of a complex of a lats protein and a cdc2 protein in a subject comprising measuring the **RNA encoding** the lats and the cdc2 proteins in a sample derived from said subject.

Group 30, claim(s), 100, drawn to the special technical feature of a kit comprising in one or more containers a complex of a lats and a cdc2 protein.

Group 31, claim(s), 100, drawn to the special technical feature of a kit comprising in one or more containers an antibody that specifically binds to a complex of a lats and a cdc2 protein.

Group 32, claim(s), 100, drawn to the special technical feature of a kit comprising in one or more containers nucleic acid probes capable of hybridizing to RNA of lats and RNA of cdc2, or pairs

of nucleic acid primers capable of priming amplification of at least a portion of a gene for lats and a gene for cdc2.

Group 33, claims(s) 101-102, 104-105 drawn to the special technical feature of a method for modulating the activity of cdc2 comprising administering a molecule that promotes lats function wherein said molecule is a lats protein.

Group 34, claims(s) 101-102, 104-105 drawn to the special technical feature of a method for modulating the activity of cdc2 comprising administering a molecule that promotes lats function wherein said molecule is a nucleic acid.

Group 35, claims(s) 101-102, 104-105 drawn to the special technical feature of a method for modulating the activity of cdc2 comprising administering a molecule that promotes lats function wherein said molecule is a lats agonist.

Group 36, claims(s) 101, 103, 106-107, drawn to the special technical feature of a method for modulating the activity of cdc2 comprising administering a molecule that inhibits or antagonizes lats function wherein said molecule is a protein derivative, or analog thereof of lats.

Group 37, claims(s) 101, 103, 106-107, drawn to the special technical feature of a method for modulating the activity of cdc2 comprising administering a molecule that inhibits or antagonizes lats function wherein said molecule is an antibody.

Group 38, claims(s) 101, 103, 106-107, drawn to the special technical feature of a method for modulating the activity of cdc2 comprising administering a molecule that inhibits or antagonizes lats function wherein said molecule is a lats antisense nucleic acid.

Group 39, claim(s) 108-109, drawn to the special technical feature of a method for screening a molecule for efficacy in treating or preventing a cancer refractory to chemotherapy or radiation therapy.

Group 40, claim(s) 110, drawn to the special technical feature of a method for screening a molecule for activity to modulate cdc2 protein levels or protein activity comprising contacting cells with the molecule, and comparing the level of cdc2 protein or activity in cells contacted with the molecule to the amount of cdc2 protein or activity in cells not contacted.

Group 41, claim(s) 110, drawn to the special technical feature of a method for screening a molecule for activity to modulate cdc2 levels comprising contacting cells with the molecule, and comparing the level of cdc2 mRNA in cells contacted with the molecule to the amount of cdc2 mRNA in cells not contacted.

Group 42, claims(s) 111-113, drawn to the special technical feature of a method for screening a molecule for activity to modulate, directly or indirectly, the formation of a complex of lats and cdc2 proteins.

The inventions listed as Groups 1-42 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature that could be shared by groups 1-42 is the mammalian lats gene or protein encoded by said gene. However, Tao et al., (US Patent No. 6,359,193, 1995) teaches a lats gene sequence that is 100% identical to SEQ ID NO:1 (see attached sequence listing) of the present invention and includes teaching the inactivation of lats genes in a non-human mammal. Thus, the present invention does not contribute any common special technical feature over the prior art.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

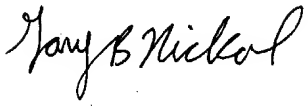
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at 571-272-0871. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
January 20, 2004



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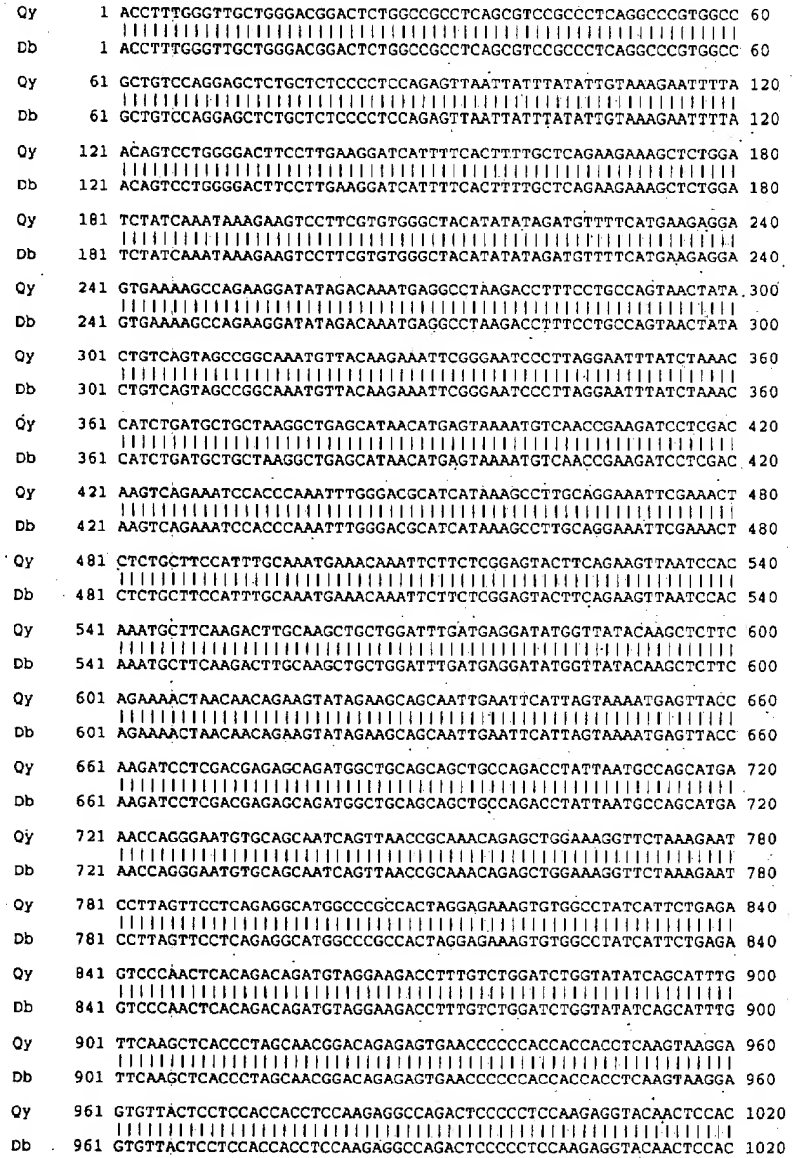

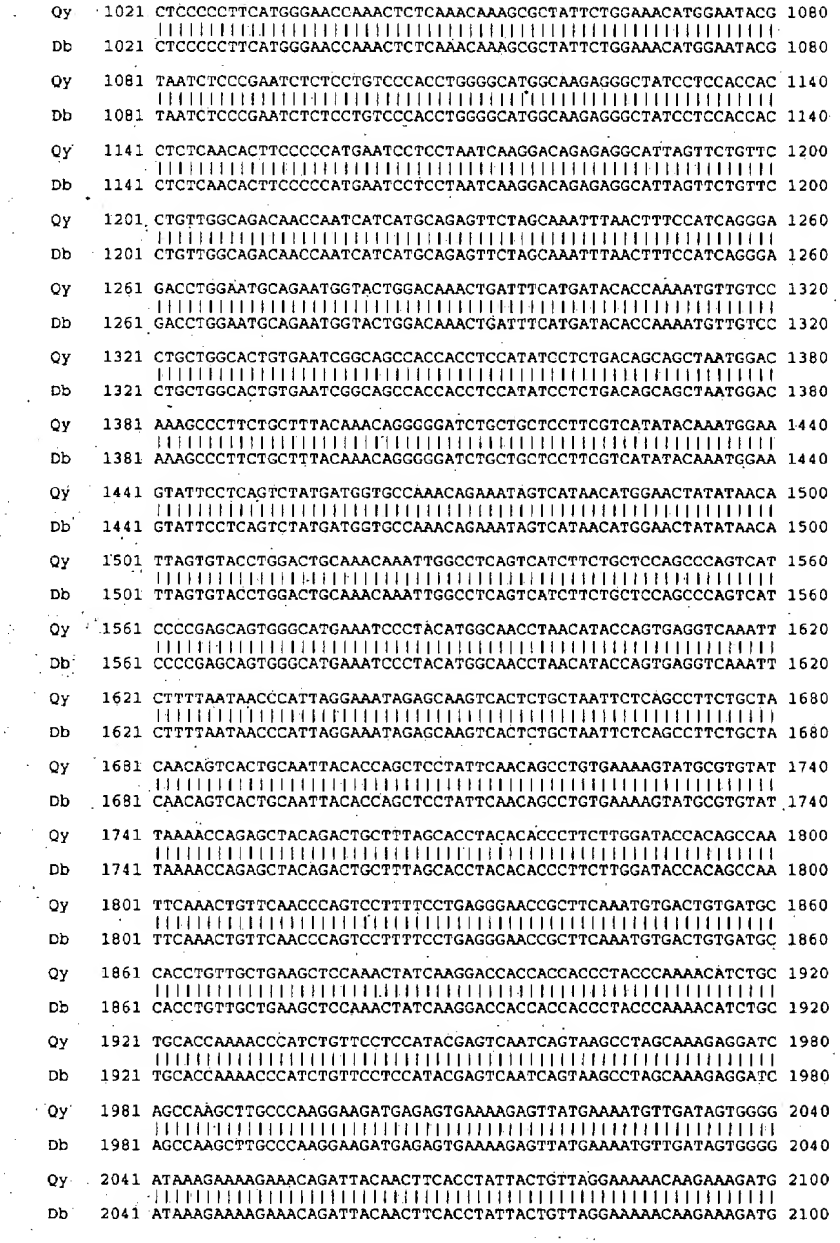

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Qy   3841 TAAATTATGAACTGAATATTATAGTCAGTTCTTGGTACTTAAAGTACTTAAAATAAGTAG 3900
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   3841 TAAATTATGAACTGAATATTATAGTCAGTTCTTGGTACTTAAAGTACTTAAAATAAGTAG 3900

Qy   3901 TGCTTTGTTTAAAAGGAGAAACCTGGTATCTATTTGTATATATGCTAAATAATTTTAAAA 3960
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Qy   3961 TACAAGAGTTTTTGAAATTTTTTT 3984
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Db   3961 TACAAGAGTTTTTGAAATTTTTTT 3984
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RESULT 2
US-09-442-100-5
; Sequence 5, Application US/09442100
; Patent No. 6359193
; GENERAL INFORMATION:
; APPLICANT: Xu, Tian
; APPLICANT: Tao, Wufan
; APPLICANT: Wang, Weiyi
; APPLICANT: Zhang, Sheng
; APPLICANT: Yu, Wan
; TITLE OF INVENTION: NUCLEOTIDE AND PROTEIN SEQUENCES OF LATS
; TITLE OF INVENTION: GENES AND METHODS BASED THEREON
; NUMBER OF SEQUENCES: 16
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Pennie & Edmonds
; STREET: 1155 Avenue of the Americas
; CITY: New York